

FEB - 8 1999  
FEB 23 P1:48

Mr. Karl Riedel  
M.K. Health Food Distributors, Inc.  
7180 Lampson Avenue  
Garden Grove, California 92841-3914

Dear Mr. Riedel:

This is in response to your letters of January 28, 1999 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that M.K. Health Food Distributors, Inc., dba Nature's Life, is making the following claims, among others, for the products:

**L-Tyrosine 500 mg**

"...helps relieve premenstrual discomfort"

**Menopause Formula**

"...reduce "hot flashes" and other feelings of discomfort..."

"...associated with menopausal hot flashes"

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for these products suggest that they are intended to treat, mitigate, or prevent disease, namely symptomatic disorders associated with menopause or premenstrual syndrome. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that these products are intended for use as drugs within the meaning of 21 U.S.C. 321(g)(1)(B), and that they are subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

Your submission also states that M.K. Health Food Distributors, Inc., dba as Nature's Life, is marketing the products "**Zinc Lozenges**" and "**Zinkers**" as dietary supplements. These product do not appear to meet the statutory definition of a dietary supplement contained in 21 U.S.C. 321(ff), and therefore, can not be marketed as dietary supplements. We explain the basis for our opinion below.

975-0163

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The term "dietary supplement" is defined in 21 U.S.C. 321(ff). 21 U.S.C. 321(ff) provides that the term means a product (other than tobacco) intended to supplement the diet that bears or contains a vitamin, a mineral, an herb or other botanical, an amino acid, a dietary substance for use by man to supplement the diet by increasing the total dietary intake, or a concentrate, metabolite, constituent, extract, or combination of any of the above ingredients. 21 U.S.C. 321(ff) further states that dietary supplements are intended for ingestion in a form described in 21 U.S.C. 350(c)(1)(B)(i) or in compliance with 21 U.S.C. 350(c)(1)(B)(ii), are not represented as conventional food or as a sole item of a meal or the dietary, and are labeled as a dietary supplement.

These products are not "intended for ingestion." As stated above, the definition of dietary supplement in 21 U.S.C. 321(ff) states that a dietary supplement is a product "intended for ingestion." The term "ingestion" has been addressed by the court in United States v. Ten Cartons, Ener-B Nasal Gel, 888 F. Supp. 381, 393-94 (E.D.N.Y.), aff'd, 72 F.3d 285 (2d Cir. 1995), which states:

The ordinary and plain meaning of the term "ingestion" means to take into the stomach and gastrointestinal tract by means of enteral administration. See Stedman's Medical Dictionary (4th Lawyer's Ed. 1976) (defining ingestion as the "introduction of food and drink into the stomach."); Webster's Third New International Dictionary (1976) (defining ingestion as "the taking of material (as food) into the digestive system.")...

The interpretation of the term "ingestion" to mean enteral administration into the stomach and gastrointestinal tract is also supported by the language of the statutory sections immediately preceding and following section 350(c)(1)(B)(ii). Section 350(c)(1)(B)(i) states that the vitamin must be intended for ingestion in tablet, capsule or liquid form. Each of these forms denotes a method of ingestion that involves swallowing into the stomach. Section 350(c)(2) states that a food is intended for ingestion in liquid form under section 350(c)(1)(B)(i) "only if it is formulated in a fluid carrier and is intended for ingestion in daily quantities measured in drops or similar small units of measure." This elaboration of "liquid form" also denotes ingestion by swallowing the fluid.

Therefore, because the term "ingestion" means introduced into the gastrointestinal tract, a product taken orally, but that delivers its contents only to the mouth or throat to exert its effect, is not subject to regulation as a dietary supplement because it is not "intended for ingestion." That your products are intended to deliver their contents prior to introduction into the gastrointestinal tract to exert their effect is evidenced by statements in your labels that the lozenges are intended for use as throat lozenges: "help soothe and nourish dry, irritated throats," "help soothe your throat," and "helps soothe sore throats."

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Please contact us if we may be of further assistance.

Sincerely,

Lynn A. Larsen, Ph.D.  
Director  
Division of Programs and Enforcement Policy  
Office of Special Nutritionals  
Center for Food Safety  
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300  
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of  
Enforcement, HFC-200  
FDA, Los Angeles District Office, Office of Compliance, HFR-PA240

cc:

HFA-224 (w/incoming)  
HFA-305 (docket 97S-0163)  
HFS-22 (CCO)  
HFS-456 (file, r/f)  
HFS-450 (r/f, file)  
HFD-310 (BWilliams)  
HFD-314 (Aronson)  
HFS-605 (Bowers)  
HFV-228 (Betz)  
HFV-232 (Brown)  
GCF-1 (Dorsey)  
f/t:HFS-456:rjm:2/8/99:docname:63542.adv:disc35

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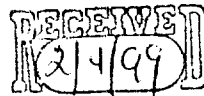
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Dr. Elizabeth A. Yetley, Ph.D., Director  
Office of Special Nutritionals - HFS-450  
United States Food & Drug Administration  
200 C Street SW, Washington, D.C. 20204



January 28, 1999

Notice of a 403(r)(6) Statement -  
Multiple Statements and Ingredients

Dr. Yetley,

This letter serves notice that M.K. Health Food Distributors, Inc., dba Nature's Life, located at 7180 Lampson Avenue, Garden Grove, California, 92841, U.S.A. is marketing a dietary supplement whose label bears 403(r)(6) statements as follows:

Helps Soothe Sore Throats

Nature's Life Zinkers<sup>™</sup> help soothe and nourish dry, irritated throats.

Vitamin C is an essential antioxidant vitamin that helps to maintain and support the immune system.

Zinc is an essential mineral for a healthy immune system, especially for the elderly who may frequently consume less than 50% of the RDI.

Vitamin C and Zinc are the dietary ingredients that are the subjects of these statements and Zinkers<sup>™</sup> Throat Lozenges is the name of the dietary supplement that is the subject of these statements.

Regards & Health,

Karl Riedel

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cc: M.K., C.M., K.C.

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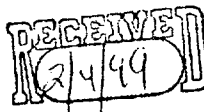
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Supports a Healthy Immune System

Nature's Life® Zinc Lozenges help to soothe your throat.

Vitamin C is an essential antioxidant vitamin that helps to maintain and support the immune system.

Zinc is an essential mineral for a healthy immune system.

Marginal zinc deficiency inhibits normal immune system function, especially in the elderly who may frequently consume less than 50% of the RDI.

Zinc and Vitamin C are the dietary ingredients that are the subject of these statements and Zinc Lozenges is the name of the dietary supplement that is the subject of these statements.

Regards & Health,

Karl Riedel

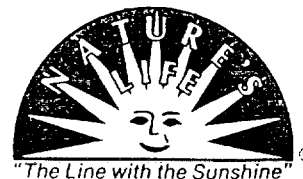
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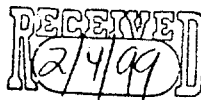
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January 28, 1999

## Notice of a 403(r)(6) Statement - Multiple Statements and Single Ingredient

Dr. Yetley,

This letter serves notice that M.K. Health Food Distributors, Inc., dba Nature's Life, located at 7180 Lampson Avenue, Garden Grove, California, 92841, U.S.A. is marketing a dietary supplement whose label bears 403(r)(6) statement as follows:

### Natural Menopause Support Menopause Formula

It may significantly help to reduce "hot flashes" and other feelings of discomfort experienced by some women during menopause caused by fluctuating hormone levels.

Phytoestrogenic compounds in Black Cohosh root extract are effective at binding to estrogen receptors.

These compounds reduce the secretion of luteinizing hormone (LH) which is associated with menopausal hot flashes.

Black Cohosh Root Extract is the dietary ingredient that is the subject of these statement and Menopause Formula is the name of the dietary supplement that is the subject of these statements.

Regards & Health,

Karl Riedel

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cc: M.K., C.M., K.C.

Also see docket 975-0163

# NATURE'S LIFE®

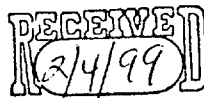
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January 28, 1999

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Multiple Statements and Single Ingredient

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This letter serves notice that M.K. Health Food Distributors, Inc., dba Nature's Life, located at 7180 Lampson Avenue, Garden Grove, California, 92841, U.S.A. is marketing a dietary supplement whose label bears 403(r)(6) statements as follows:

Helps Relieve Stress and Irritability

Tyrosine helps relieve mild stress and anxiety; helps night shift workers stay alert and helps relieve premenstrual discomfort.

I-Tyrosine is the dietary ingredient that is the subject of these statements and I-Tyrosine 500 mg is the name of the dietary supplement that is the subject of these statements.

Regards & Health,

Karl Riedel

encl: Two Copies of this Notice

cc: M.K., C.M., K.C.

*Also see docket 97S-0163*